



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER CIN-WL-01-7055

April 10, 2001

Michael Bensman
President
Minster Farmers Cooperative Exchange, Inc.
292 West Fourth Street
Minster, OH 45865

Dear Mr. Bensman:

An inspection of your Minster, Ohio feed mill was conducted by a Food and Drug Administration (FDA) investigator on February 27, 2001. This inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and distributed by your facility to be misbranded within the meaning of Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found your firm fails to label feeds which contain, or may contain, prohibited materials with the required cautionary statement "**Do not feed to Cattle or Other Ruminants**". We suggest the statement be distinguished by different type size, color, or other means of highlighting so it is easily noticed by the purchaser.

During the inspection, the investigator observed the label on bulk storage bin #1 had the cautionary statement, but an identical label found in a drawer had the cautionary statement blacked out. This is a potentially confusing situation which could result in inappropriate sale or use of prohibited materials.

Some of your suppliers may have indicated that they are no longer manufacturing products with prohibited materials, but it is possible that they are still shipping existing inventories of the old formulation. You should examine the labels of incoming shipments carefully. Unless you have written assurances from an authoritative source to the contrary, you should assume any product bearing the cautionary statement contains prohibited materials and handle that product in accordance with Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed.

Page -2-

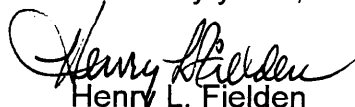
This letter is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operations, including operations at other locations, and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in 15 days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Deborah Grelle, Director of Compliance, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Oh 45237, telephone (513) 679-2700 extension 160.

Sincerely yours,


Henry L. Fielden
District Director

Enclosure: Small Entity Compliance Guide

Cc: David Schleich, Chief Plant Industry Division
Ohio Department of Agriculture
8995 East Main Street
Reynoldsburg, OH 43068-3399